DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Gel-One
Patent Nos. 5,763,504; 6,031,017; 6,602,859
Docket Nos. FDA-2011-E-0679
FDA-2011-E-0680
FDA-2011-E-0681

JUN 5 2012

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the applications for patent term extension for U.S. Patent Nos. 5,763,504; 6,031,017; and 6,602,859; filed by Seikagaku Kogyo Kabushiki Kaisha (Seikagaku Corporation) under 35 U.S.C. 156. The medical device claimed by the patents is Gel-One (sodium hyaluronate), which was assigned premarket approval application (PMA) No. P080020.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). However, our records also indicate that Gel-One does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredient, sodium hyaluronate, has been previously approved for commercial marketing or use in Ferring Pharmaceuticals, Inc.'s premarket approval application, P010029. In addition, the base of the active ingredient in the Gel-One device has been previously approved for commercial marketing or use in other premarket approval applications, including Fidia Farmaceutici SPA's Hyalgan; Genzyme Corporation's Synvisc-One; Quintiles, Inc.'s Supartz Dispo; and Anika Therapeutics, Inc.'s Orthovisc High Molecular Weight Hyaluronan.

The PMA was approved on March 22, 2011, which makes the submission of the patent term extension application on May 18, 2011, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Susan J. Mack, Esq.
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